

October 21, 2003

Ms. Linda Jackowiak
EH & S Manager
Enzon Pharmaceuticals, Inc.
6925 Guion Road
Indianapolis, IN 46268

Dear Ms. Jackowiak:

Re: Exempt Operation Status,
097-17954-00511

The application from Enzon Pharmaceuticals, Inc. received on September 2, 2003, has been reviewed. Based on the data submitted and the provisions in 326 IAC 2-1.1-3, it has been determined that the following pharmaceuticals manufacturing located at 6925 Guion Road, Indianapolis, Indiana, is classified as exempt from air pollution permit requirements:

- (a) One (1) virgin methylene chloride bulk storage tank, identified as T-401. Maximum storage capacity of 6140 gallons. Installed in 1996.
- (b) One (1) lipids prep tank, identified as T-101. Maximum storage capacity of 500 gallons. Utilized to prep lipids with methylene chloride. Installed in 1996.
- (c) One (1) Abelcet batch product mix tank, identified as R-216A. Maximum capacity of 794 gallons. Estimated maximum batch production capacity of 78 batches per year. The batch production process involves and includes distillation to remove methylene chloride from the final product. Installed in 1996.
- (d) One (1) waste methylene chloride storage tank, identified as T-405. Maximum capacity of 5000 gallons. Installed in 1996.
- (e) One (1) natural gas fired boiler, identified as Boiler # 1. Maximum rated capacity of five (5.0) million Btu per hour. Installed prior to 1996.
- (f) Isopropyl Alcohol use in spot cleaning and sanitization of pharmaceutical manufacturing equipment. Estimated maximum usage of 8000 pounds per year.

The following conditions shall be applicable:

- (a) Pursuant to 326 IAC 5-1-2 (Opacity Limitations) except as provided in 326 IAC 5-1-3 (Temporary Exemptions), opacity shall meet the following:
 - (1) Opacity shall not exceed an average of thirty percent (30%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.
 - (2) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of 15 minutes (60 readings) in a 6-hour period as measured according to 40 CFR 60,

Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor in a six (6) hour period.

- (b) Pursuant to 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes), particulate matter (PM) from the product mixing tank R-216A shall be limited by the following:

Interpolation and extrapolation of the data for the process weight rate up to sixty thousand (60,000) pounds per hour shall be accomplished by use of the equation:

$$E = 4.10 P^{0.67} \quad \text{where } E = \text{rate of emission in pounds per hour and} \\ P = \text{process weight rate in tons per hour}$$

At a maximum process rate of 2661.8 kilograms or 2.9 tons per hour, particulate emissions shall not exceed 8.4 pounds or particulate per hour from product mixing tank R-216A.

- (c) Pursuant to 326 IAC 6-2-1(d), particulate emissions from the combustion of fuel for indirect heating facilities receiving permits to construct after September 21, 1983 shall be limited by 326 IAC 6-2-4 (Emission Limitations for Facilities Specified in 326 IAC 6-2-1(d)). Pursuant to 326 IAC 6-2-4, this limitation is based on the following equation:

$$Pt \leq 1.09 / (Q^{0.26})$$

Where: Pt = Pounds of particulate matter emitted per million Btu (lb/mmBtu) heat input.

Q = Total source maximum operating capacity rating in million Btu per hour (mmBtu/hr) heat input.

Pursuant to 326 IAC 6-2-4(a), for Q less than ten (10.0) million Btu per hour, Pt shall not exceed 0.6 pounds per million Btu heat input. Therefore, pursuant to 326 IAC 6-2-4 (Particulate Emission Limitations for Sources of Indirect Heating), particulate emissions from Boiler # 1 shall not exceed 0.6 pounds per million Btu heat input.

- (d) Distillation equipment shall be in operation at all times when Abelcet manufacturing in Tank R-216A is in operation.
- (e) Pursuant to 40 CFR 60.486(i)(2) (Subpart VV -Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry), Enzon Pharmaceuticals shall keep in a log that is readily accessible records of an analysis demonstrating that equipment is not in VOC (Volatile Organic Compound) service.

This exemption is the first air approval issued to this source.

An application or notification shall be submitted in accordance with 326 IAC 2 (Permit Review Rules) to the Indiana Department of Environmental Management Office of Air Quality (OAQ) and the City of Indianapolis Office of Environmental Services (OES) if the source proposes to construct new emission units, modify existing emission units, or otherwise modify the source.

Sincerely,

Enzon Pharmaceuticals, Inc
Indianapolis, IN
Permit Reviewer: MBC

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Original Signed by John B. Chavez
John B. Chavez
Administrator

MBC

cc: file (2 copies)
Mindy Hahn, IDEM, OAQ

**Indiana Department of Environmental Management
Office of Air Quality
and
City of Indianapolis
Office of Environmental Services**

Technical Support Document (TSD) for an Exemption

Source Background and Description

Source Name: Enzon Pharmaceuticals, Inc.
Source Location: 6925 Guion Road, Indianapolis, Indiana 46268
County: Marion
SIC Code: 2834
Operation Permit No.: 097-17954-00511
Permit Reviewer: M. Caraher

The City of Indianapolis Office of Environmental Services (OES) and the Indiana Department of Environmental Management Office of Air Quality (OAQ) have reviewed an Exemption application from Enzon Pharmaceuticals, Inc. relating to the operation of an existing stationary source manufacturing pharmaceuticals under a Standard Industrial Classification (SIC) Code of 2834 (establishments primarily engaged in manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use).

Permitted Emission Units and Pollution Control Equipment

The source consists of the following permitted emission units and pollution control devices:

- (a) One (1) virgin methylene chloride bulk storage tank, identified as T-401. Maximum storage capacity of 6140 gallons. Installed in 1996.
- (b) One (1) lipids prep tank, identified as T-101. Maximum storage capacity of 500 gallons. Utilized to prep lipids with methylene chloride. Installed in 1996.
- (c) One (1) Abelcet batch product mix tank, identified as R-216A. Maximum capacity of 794 gallons. Estimated maximum batch production capacity of 78 batches per year. The batch production process involves and includes distillation to remove methylene chloride from the final product. Installed in 1996.
- (d) One (1) waste methylene chloride storage tank, identified as T-405. Maximum capacity of 5000 gallons. Installed in 1996.
- (e) One (1) natural gas fired boiler, identified as Boiler # 1. Maximum rated capacity of five (5.0) million Btu per hour. Installed prior to 1996.
- (f) Isopropyl Alcohol use in spot cleaning and sanitization of pharmaceutical manufacturing equipment. Estimated maximum usage of 8000 pounds per year.

Air Pollution Control Justification as an Integral Part of the Process

Enzon Pharmaceuticals, Inc. has submitted the following justification such that the distillation process for Abelcet batch production be considered as an integral part of the Abelcet batch production process:

- (a) Manufacture of the product cannot occur without distillation: As a pharmaceutical manufacturer, Enzon Pharmaceuticals is bound to Abelcet production by a specific formulation and process. The current production process for Abelcet manufacturing is the only production process approved by the Food and Drug Administration (FDA) for our formulation and part of this production process requires that methylene chloride, introduced into the process as a processing aid, be distilled to separate it from the end product. To perform this production process in any other way, has the means of affecting product quality and, therefore, potential for patient harm. The distillation process is the only method that allows for the removal of methylene chloride from the product in such a way that the product is not significantly removed in the process as well.
- (b) The distillation unit serves a purpose other than pollution control: The distillation process' primary purpose is not as a pollution control device. Distillation occurs to remove methylene chloride from the product.
- (c) The distillation process serves an economic benefit: The current process for Abelcet production is the only process approved by the FDA. To vary from this process (to change from a distillation process to another means of removal) would require extensive reformulation time, testing and submission to the FDA for approval. To pursue another option for removal of methylene chloride from the product would be a tremendous waste of time and money. Additionally, distillation allows for removal of methylene chloride from the product in such a way that other impurities in recovered methylene chloride are minimized or eliminated. Because of the level of purity of the recovered methylene chloride, Enzon Pharmaceuticals does not have to pay for this material to be treated as a hazardous waste. The cost savings for non treatment and not having to have the material incinerated is significant.

IDEM, OAQ and OES have evaluated the justifications and agree that distillation equipment will be considered as an integral part of the Abelcet production process. Therefore, the permitting level will be determined using the potential to emit after the distillation equipment. Operating conditions in the proposed permit will specify that the distillation equipment shall operate at all times when Abelcet manufacturing in Tank R-216A is in operation.

Stack Summary

Stack ID	Operation	Height (feet)	Diameter (feet)	Flow Rate (dscfm)	Temperature (°F)
T-401	Storage Tank	12	18	NA	NA
T-101	Storage Tank	5	8.34	NA	NA
R-216A	Product Mix Tank	5	11	NA	84
T-405	Storage Tank	12	18	NA	NA
Boiler # 1	Boiler # 1	21	1.17	43700 *	> 200

* based on F_g factor of 8740 dscf/MMBtu heat input.

Enforcement Issue

There are no enforcement actions pending.

Recommendation

The staff recommends to the Administrator that the Exemption be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

A complete application for the purposes of this review was received on September 2, 2003. Additional information was obtained during a plant inspection and source meeting on October 6, 2003. Additional information in regards to integral controls, potential emissions and boiler stack parameters was received on October 20, 2003.

Emission Calculations

See Appendix A pages 1 through 3 of 3 of this document for detailed emissions calculations.

Potential To Emit

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as “the maximum capacity of a stationary source or emissions unit to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA, the department, or the appropriate local air pollution control agency.”

Pollutant	Potential To Emit (tons/year)
PM	0.2
PM-10	0.2
SO ₂	0.0
VOC	4.0
CO	1.8
NO _x	2.2

HAP's	Potential To Emit (tons/year)
Methylene Chloride	6.5
Hexane	0.0
TOTAL	6.5

- (a) The potential to emit (as defined in 326 IAC 2-7-1(29)) of each criteria pollutant is less than 100 tons per year. Therefore, the source is not subject to the provisions of 326 IAC 2-7 (Part 70 Permit Program).
- (b) The potential to emit (as defined in 326 IAC 2-7-1(29)) of any single HAP is less than ten (10) tons per year and the potential to emit (as defined in 326 IAC 2-7-1(29)) of any combination of HAPs is less than twenty-five (25) tons per year. Therefore, the source is not subject to the provisions of 326 IAC 2-7 (Part 70 Permit Program).
- (c) The potential to emit of the source is less than each threshold identified in 326 IAC 2-1.1-3(e)(1) (Permit Review Rules: Exemptions). Therefore, this source qualifies as an Exemption pursuant to 326 IAC 2-1.1-3 (Permit Review Rules: Exemptions).
- (d) Fugitive Emissions
Since this type of operation is in one of the twenty-eight (28) listed source categories under 326 IAC 2-2, specifically, “chemical process plants,” and since there are no applicable New Source Performance Standards that were in effect on August 7, 1980, fugitive emissions are counted toward determination of PSD and Emission Offset applicability.

Actual Emissions

No previous emission data has been received from the source.

County Attainment Status

The source is located in Marion County.

Pollutant	Status
PM-10	unclassifiable
SO ₂	maintenance attainment
NO ₂	attainment
Ozone	maintenance attainment
CO	attainment
Lead	unclassifiable

- (a) Volatile organic compounds (VOC) are precursors for the formation of ozone. Therefore, VOC emissions are considered when evaluating the rule applicability relating to the ozone standards. Marion County has been designated as attainment or unclassifiable for ozone. Therefore, VOC emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.
- (b) Marion County has been classified as attainment or unclassifiable for PM-10, SO₂, NO_x, CO and Lead. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.
- (c) Fugitive Emissions
Since this type of operation is in one of the 28 listed source categories under 326 IAC 2-2, 40 CFR 52.21, or 326 IAC 2-3, specifically, "chemical process plants," and since there are no applicable New Source Performance Standards that were in effect on August 7, 1980, the fugitive emissions are counted toward determination of PSD and Emission Offset applicability.

Source Status

Existing Source PSD Definition (emissions after controls, based on 8,760 hours of operation per year at rated capacity and/ or as otherwise limited):

Pollutant	Emissions (ton/yr)
PM	0.2
PM10	0.2
SO ₂	0.0
VOC	4.0
CO	1.8
NO _x	2.2

- (a) This existing source is not a major stationary source because no attainment regulated pollutant is emitted at a rate of one hundred (100) tons per year or more, and it is in one of the twenty eight (28) listed source categories, specifically, "chemical process plants."
- (b) These emissions were based on the application for Exemption status for this existing stationary source submitted on September 2, 2003.

Part 70 Permit Determination

326 IAC 2-7 (Part 70 Permit Program)

This existing source, including the emissions from this Exemption 097-17954-00571, is not subject to the Part 70 Permit requirements because the potential to emit (PTE) of:

- (a) each criteria pollutant is less than 100 tons per year,
- (b) a single hazardous air pollutant (HAP) is less than 10 tons per year, and
- (c) any combination of HAPs is less than 25 tons/year.

This is the first air approval issued to this source.

Federal Rule Applicability

- (a) Storage tanks T-401, T-405, T-101 and product mixing tank R-216A are each not subject to the requirements of the New Source Performance Standard, 326 IAC 12, (40 CFR 60.110b, Subpart Kb (Standards of Performance for Volatile Organic Liquid Storage Vessels (Including Petroleum Liquid Storage Vessels) for Which Construction, Reconstruction, or Modification Commenced After July 23, 1984)), because each tank has a storage capacity of less than 40 cubic meters (10,568 gallons) and each tank stores or processes methylene chloride which, pursuant to 40 CFR 51.100(s)(1) (Requirements for Preparation, Adoption, and Submittal of Implementation Plans), is excluded as a volatile organic compound (VOC) in the definition of a VOC. Therefore, the provisions of 40 CFR 60.110b Subpart Kb do not apply to Storage tanks T-401, T-405, T-101 and product mixing tank R-216A.
- (b) This stationary source manufacturing pharmaceuticals is subject to the requirements of 326 IAC 12, (40 CFR 60.480, Subpart VV (Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemicals Manufacturing Industry)) because the source commenced operation after the rule applicability date of January 5, 1981, it meets the definition of a synthetic organic chemicals manufacturing industry (pursuant to 40 CFR 60.481) and it may produce, as an intermediate product, one or more of the chemicals listed in 40 CFR 60.489 (specifically, methylene chloride). However, this source has no process units or affected facilities that are in VOC service. Pursuant to 40 CFR 60.481, in VOC service means that the piece of equipment contains or contacts a process fluid that is at least ten percent (10%) VOC by weight. This source processes methylene chloride in Abelcet manufacturing which, pursuant to 40 CFR 51.100(s)(1) (Requirements for Preparation, Adoption, and Submittal of Implementation Plans), is excluded as a volatile organic compound (VOC) in the definition of a VOC.

Because this source has no equipment in VOC service, Enzon Pharmaceuticals may apply for one or more of the exemptions listed in 40 CFR 60.480(d) such that Subpart VV will not apply. Pursuant to 40 CFR 60.480(d)(5), any affected facility that has no equipment in VOC service is exempt from the rule as long as records are kept pursuant to 40 CFR 60.486(i). Specifically, pursuant to 40 CFR 60.486(i)(2), Enzon Pharmaceuticals shall keep in a log that is readily accessible records of an analysis demonstrating that equipment is not in VOC service.

- (c) This stationary source manufacturing pharmaceuticals is not subject to the requirements of 326 IAC 12, (40 CFR 60.610, Subpart III (Standards of Performance for Volatile Organic Compound Emissions from the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Process)) because this source does not produce any of the chemicals listed in 40 CFR 60.617 as a product, co-product, by-product or intermediate. Therefore, the provisions of 40 CFR 60.610 do not apply to this source.
- (d) Boiler # 1 is not subject to the New Source Performance Standard, 326 IAC 12, (40 CFR 60.40c, Subpart Dc (Standards of Performance for Small Industrial-Commercial-Institutional

Steam Generating Units)) because this boiler has a maximum design heat input capacity of less than ten (10) million Btu per hour. Therefore, the provisions of 40 CFR 60.40c Subpart Dc do not apply to Boiler # 1.

- (e) This stationary source manufacturing pharmaceuticals is not subject to the requirements of 326 IAC 14, (40 CFR Part 61, National Emission Standards for Hazardous Air Pollutants (NESHAPs)), because there are no applicable provisions of 40 CFR Part 61 to pharmaceuticals manufacturing.
- (f) This stationary source manufacturing pharmaceuticals is not subject to the requirements of 326 IAC 20, (40 CFR 63.1250, Subpart GGG (National Emission Standards for Pharmaceuticals Production)) because this source is not a major Hazardous Air Pollutant (HAP) source. The potential to emit of any single HAP is less than ten (10) tons per year and the potential to emit of any combination of HAPs is less than twenty-five (25) tons per year. Therefore, the provisions of 40 CFR 63.1250, Subpart GGG do not apply to this source.
- (g) The requirements of Section 112(j) of the Clean Air Act (40 CFR Part 63.50 through 63.56) are not applicable to this source because the source does not have the potential to emit ten (10) tons per year or greater of a single HAP or twenty five (25) tons per year or greater of any combination of HAP.

State Rule Applicability - Entire Source

326 IAC 2-1.1-3 (Permit Review Rules: Exemptions)

This source has the potential to emit less than ten (10) tons per year of a single hazardous air pollutant (HAP), as defined under Section 112(b) of the Clean Air Act, or less than twenty-five (25) tons per year of any combination of HAPs. Therefore, pursuant to 326 IAC 2-1.1-3(d)(4), the requirements of 326 IAC 2-5.1-2 for registrations and 326 IAC 2-5.1-3 for permits do not apply to this source.

Pursuant to 326 IAC 2-1.1-3(e)(1), the requirement to submit an application, does not apply to the following:

- (a) New sources or modifications to existing sources that are proposed to be operated or constructed, that have the potential to emit less than the following amounts:
 - (1) Five (5) tons per year of either particulate matter (PM) or particulate matter with an aerodynamic diameter less than ten (10) micrometers (PM₁₀).
 - (2) Ten (10) tons per year of sulfur dioxide (SO₂).
 - (3) Ten (10) tons per year of nitrogen oxides (NO_x).
 - (4) Ten (10) tons per year of volatile organic compounds (VOC) for sources or modifications that are not described by clause (5) below.
 - (5) Five (5) tons per year of volatile organic compounds (VOC) for sources or modifications that require the use of air pollution control equipment to comply with the applicable provisions of 326 IAC 8.
 - (6) Twenty-five (25) tons per year of carbon monoxide (CO).
 - (7) Two-tenths (0.2) ton per year of lead (Pb).

This stationary source, in existence since 1996, is seeking its first air emissions approval. This source has not under gone a modification or new construction since 1996 and the potential to emit of the source is less than each threshold identified in 326 IAC 2-1.1-3(e)(1) (Permit Review Rules: Exemptions). Therefore, this source qualifies as an Exemption pursuant to 326 IAC 2-1.1-3 (Permit Review Rules: Exemptions).

326 IAC 2-2 (Prevention of Significant Deterioration (PSD) Requirements)

This source is on the list of twenty eight (28) source categories identified under 326 IAC 2-2-1(y)(1)

(Prevention of Significant Deterioration (PSD) Requirements), specifically, "chemical process plants," because "chemical process plants," under the PSD rules, include sources operating under a Standard Industrial Classification (SIC) Code of 28. This existing stationary source manufactures pharmaceuticals under a Standard Industrial Classification (SIC) Code of 2834 (establishments primarily engaged in manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use) and has the potential to emit less than one hundred (100) tons per year of any criteria pollutant, and is, therefore, not a major source pursuant to 326 IAC 2-2 (Prevention of Significant Deterioration (PSD) Requirements).

This existing minor PSD source commenced operation after August 8, 1977, specifically in 1996, and has not had a modification or new construction that was a major modification under the PSD rules. Therefore, 326 IAC 2-2 (Prevention of Significant Deterioration (PSD) Requirements) does not apply to this source. This stationary source, in existence since 1996, is seeking its first air emissions approval.

326 IAC 2-4.1 (New Source Toxics Control)

This existing source commenced operation prior to July 27, 1997 and does not have the potential to emit hazardous air pollutant (HAP) emissions of equal to or greater than ten (10) tons per year for any individual HAP nor does this source have the potential to emit HAP of equal to or greater than twenty five (25) tons per year for any combination of HAP. This source did not undergo a construction or a reconstruction of a major HAP source after July 27, 1997. Therefore, this source is not subject to 326 IAC 2-4.1 (New Source Toxics Control).

326 IAC 2-6 (Emission Reporting)

This source is located in Marion County and the potential to emit VOC and NO_x are each less than ten (10) tons per year. The source is one of the twenty-eight (28) listed sources, specifically, "chemical process plants," but its potential to emit PM₁₀ is less than one-hundred (100) tons per year including fugitive emissions, therefore, 326 IAC 2-6 (Emission Reporting) does not apply to this source.

326 IAC 5-1 (Opacity Limitations)

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Exemptions), opacity shall meet the following, unless otherwise stated in this permit:

- (a) Opacity shall not exceed an average of thirty percent (30%) any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.
- (b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings) as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

326 IAC 6-1-2(a) (Nonattainment Area Limitations)

Sources or facilities located in Marion County which have the potential to emit greater than one hundred (100) tons per year of particulate matter or that have actual emissions greater than ten (10) tons per year and are not otherwise limited by 326 IAC 6-1-2(b) through (g) or 326 IAC 6-1-12 shall not exceed three hundredth (0.03) grains per dry standard cubic foot of exhaust air. This source does not have the potential to emit greater than one hundred (100) tons per year of particulate matter nor does the source have actual emissions greater than ten (10) tons per year. This source is not otherwise limited by 326 IAC 6-1-2(b) through (g) and is not specifically identified in 326 IAC 6-1-12. Therefore, 326 IAC 6-1-2(a) (Nonattainment Area Limitations) does not apply to this source.

326 IAC 8-1-6 (Volatile Organic Compound Rules; General Reduction Provisions Relating to VOC Rules)

Pursuant to 326 IAC 8-1-6 (Volatile Organic Compound Rules; General Reduction Provisions Relating to VOC Rules), new facilities, as of January 1, 1980, which have potential VOC emissions of twenty five (25) tons or more per year and which are not otherwise regulated by other provisions of 326 IAC

8 (Volatile Organic Compound Rules) shall reduce emissions using Best Available Control Technology (BACT). This source, otherwise not regulated by any other provision of 326 IAC 8 (Volatile Organic Compound Rules), commenced operation after January 1, 1980 but does not have the potential to emit twenty five (25) tons or more per year of VOC. Therefore, this source is not subject to 326 IAC 8-1-6 (Volatile Organic Compound Rules; General Reduction Provisions Relating to VOC Rules).

State Rule Applicability - Individual Facilities

Storage tanks T-401, T-405, T-101 and product mixing tank R-216A

326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes)

Pursuant to 326 IAC 6-3-2 (Particulate Emission Limitations for Manufacturing Processes), particulate matter (PM) from the product mixing tank R-216A shall be limited by the following:

Interpolation and extrapolation of the data for the process weight rate up to sixty thousand (60,000) pounds per hour shall be accomplished by use of the equation:

$$E = 4.10 P^{0.67} \quad \text{where } E = \text{rate of emission in pounds per hour and} \\ P = \text{process weight rate in tons per hour}$$

At a maximum process rate of 2661.8 kilograms or 2.9 tons per hour, particulate emissions shall not exceed 8.4 pounds or particulate per hour from product mixing tank R-216A.

326 IAC 8-5-3 (Synthesized Pharmaceutical Manufacturing Operations)

This Section applies to the manufacture of pharmaceutical products by chemical synthesis. This Section applies to all facilities emitting volatile organic compounds (VOC), including reactors, distillation units, dryers, storage of VOC, transfer of VOC, extraction equipment, filters, crystallizers and centrifuges that have the potential to emit fifteen (15) pounds or more of VOC per day. This pharmaceuticals manufacturing source does not emit VOC from reactors, distillation units, dryers, storage, transfer, extraction equipment, filters, crystallizers or centrifuges and does not have the potential to emit fifteen (15) pounds or more of VOC per day. This source utilizes methylene chloride in pharmaceuticals manufacturing which, pursuant to 40 CFR 51.100(s)(1) (Requirements for Preparation, Adoption, and Submittal of Implementation Plans), is excluded as a volatile organic compound (VOC) in the definition of a VOC. Therefore, the provisions of 326 IAC 8-5-3 (Synthesized Pharmaceutical Manufacturing Operations) do not apply to this source.

326 IAC 8-9-1 (Volatile Organic Liquid Storage Vessels)

This rule applies to stationary vessels used to store volatile organic liquid that are located in Clark, Floyd, Lake or Porter County. This source is located in Marion County and storage tanks T-401, T-405, T-101 and product mixing tank R-216A store or process methylene chloride which, pursuant to 40 CFR 51.100(s)(1) (Requirements for Preparation, Adoption, and Submittal of Implementation Plans), is excluded as a volatile organic compound (VOC) in the definition of a VOC. Therefore, the provisions of 326 IAC 8-9-1 (Volatile Organic Liquid Storage Vessels) do not apply to this source.

Boiler # 1

326 IAC 6-2 (Particulate Emission Limitations for Sources of Indirect Heating)

Pursuant to 326 IAC 6-2-1(d), particulate emissions from the combustion of fuel for indirect heating facilities receiving permits to construct after September 21, 1983 shall be limited by 326 IAC 6-2-4 (Emission Limitations for Facilities Specified in 326 IAC 6-2-1(d)). Pursuant to 326 IAC 6-2-4, this limitation is based on the following equation:

$$Pt \leq 1.09 / (Q^{0.26})$$

Where: Pt = Pounds of particulate matter emitted per million Btu (lb/mmBtu) heat input.

Q = Total source maximum operating capacity rating in million Btu per hour (mmBtu/hr) heat input.

Q for the total source maximum operating capacity rating in million Btu per hour (mmBtu/hr) heat input for this source (Boiler # 1 only) equals five (5.0) million Btu per hour. Pursuant to the above equation listed in 326 IAC 6-2-4, Pt equals 0.72 pounds of particulate matter emitted per million Btu heat input.

Pursuant to 326 IAC 6-2-4(a), for Q less than ten (10.0) million Btu per hour, Pt shall not exceed 0.6. Therefore, pursuant to 326 IAC 6-2-4 (Particulate Emission Limitations for Sources of Indirect Heating), particulate emissions from Boiler # 1 shall not exceed 0.6 pounds per million Btu heat input.

Based on an AP-42 emission factor of 7.6 pounds of PM per million cubic feet of natural gas, Boiler # 1 is in compliance at an emission rate of 0.01 pounds of PM per million Btu ($7.6 \# \text{ PM/MMCF} \times \text{MMCF}/1000 \text{ MMBtu} = 0.01 \# \text{ PM/MMBtu}$).

Isopropyl Alcohol use in spot cleaning and sanitization of pharmaceutical manufacturing equipment

326 IAC 8-3 (Organic Solvent Degreasing Operations)

This source does not perform organic solvent cleaning or degreasing in a cold cleaner tank, open top vapor degreaser or conveyorized degreasing operation. Spot cleaning and sanitization of miscellaneous pharmaceutical manufacturing production equipment is performed in place using isopropyl alcohol. Therefore, the equipment and work practice standards for organic solvent degreasing operations of 326 IAC 8-3 (Organic Solvent Degreasing Operations) do not apply to source.

Conclusion

The operation of this stationary source manufacturing pharmaceuticals shall be subject to the conditions of the attached Exemption 097-17954-00511.

APPENDIX A

Appendix A: Emission Calculations

TSD App A page 1 of 3

Storage Tank
Breathing & Working
Losses

Company Name: Enzon Pharmaceuticals, Inc.
Address City IN ZIP: 6925 Guion Road, Indpls., IN 46268
CP:
Plt ID: 097-17954-00511
Reviewer: M. Caraher
Date: 10/8/2003

	TA NK				
	T-401	T-405	T-101	R-216	
Tank Height (ft)	12	12	5	5	
Tank Dia (ft)	9	9	4.17	5.5	
Working Volume (gal)	6140	5000	500	794	
Turnovers/year	9.22	8	78	78	
Net Thruput (gal/yr)	56610.8	40000	39000	61580	
Heated Tank? (Y/N)	N	N	Y	Y	
Shell Color / Shade	Aluminum / Specular	Aluminum / Specular	Aluminum / Specular	Aluminum / Specular	
Shell Condition	Good	Good	Good	Good	
Roof Color / Shade	Aluminum / Specular	Aluminum / Specular	Aluminum / Specular	Aluminum / Specular	
Roof Condition	Good	Good	Good	Good	
Roof Type	Dome	Dome	Dome	Dome	
Roof Height (ft)	1.6	1.6	0.67	1	
Roof Radius (ft)	9	9	4.17	5.5	
Breather Vent Settings					
Vacuum Settings (psig)	-0.05	-0.05	0*	0*	
Pressure Settings (psig)	0.05	0.05	0*	0*	
Breathing Losses (lbs/yr)	1057.57	1057.57	30.46	0	
Working Losses (lbs/yr)	600.8	424.57	233.14	77.26	
Total Losses (lbs/yr)	1653.37	1482.14	263.6	77.26	
Total Losses (tons/yr)	0.83	0.74	0.13	0.04	1.74

Data used in TANKS4.0 to calculate breathing and working losses.

0* denotes program default for heated tanks in TANKS4.0

Appendix A: Emission Calculations

TSD App A page 2 of 3

Tank R-216A
Batch Production
Losses & IPA use

Company Name: Enzon Pharmaceuticals, Inc.
Address City IN ZIP: 6925 Guion Road, Indpls., IN 46268
CP:
Plt ID: 097-17954-00511
Reviewer: M. Caraher
Date: 10/20/2003

Maximum # Abelcet
batches per year
78

2563.0	kg virgin MeCl ₂ per batch input
2506.6	kg MeCl ₂ distilled per batch as output
56.4	kg MeCl ₂ per batch loss

4398.1	kg per year MeCl ₂ loss
9675.8	lbs per year MeCl ₂ loss @ 2.2 lbs/kg
4.8	tons per year MeCl ₂ loss

97.80%	minimum distillation efficiency in methylene chloride recovery
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from 10/20/03 additional info submittal

Max Estimated
Isopropyl Alcohol Sanitization
Use (lbs/yr)
8000

4.0	tons VOC from spot usage of IPA in sanitation
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0511calc.xls

Appendix A: Emission Calculations

TSD App A page 3 of 3

Boiler # 1

Natural Gas Combustion < 100 MMBtu/hr

Company Name: Enzon Pharmaceuticals, Inc.
Address City IN ZIP: 6925 Guion Road, Indpls., IN 46268
CP:
Plt ID: 097-17954-00511
Reviewer: M. Caraher
Date: 10/8/2003

Heat Input Capacity
MMBtu/hr

Potential Throughput
MMCF/yr

5.0

43.8

	Pollutant						Highest HAP Hexane
	PM	PM10	SO2	NOx	VOC	CO	
Emission Factor in lb/MMCF	7.6	7.6	0.6	100.0	5.5	84.0	1.8
Potential Emission in tons/yr	0.2	0.2	0.0	2.2	0.1	1.8	0.04

Methodology

MMBtu = 1,000,000 Btu

MMCF = 1,000,000 cubic feet of gas

Emission Factors for NOx: uncontrolled = 100, Low NOx = 17, Flue Gas Recirculation = 36

Potential Throughput (MMCF) = Heat Input Capacity (MMBtu/hr) x 8760 hrs/yr x 1 MMCF/1,000 MMBtu

Emission Factors from AP-42 (7/98), Chapter 1.4 Tables 1.4-1, 1.4-2 and 1.4-3

Emissions (tons/yr) = Throughput (MMCF/yr) x Emission Factor (lb/MMCF) / 2000 lb/ton

0511calc.xls